

K962605

PRO-GUARD DOUBLE DUTY CSR WRAP 510(K) SUMMARY

(1) SUBMITTED BY:

William B. Youngmark
Director, QC
Surgicot, Inc.
4018 Patriot Drive
RTP, NC 27709
919-361-0419
1/29/97

MAR 11 1997

(2) RE: K962605

PRO-GUARD DOUBLE DUTY CSR WRAP

(3) Single use non-woven wraps are well known and have been in use by health care providers for many years. Materials commonly used in these wraps include pure cellulose (Dexter, Surgicot Surgiwrap), polyester/cellulose (Surgicot Pro-Guard Regular and Heavy Duty) and 100% polypropylene (Kimberly-Clark Kinguard Regular, Heavy Duty, Ultra and One Step; American Threshold Secure-Wrap). Pro-Guard Double Duty is substantially equivalent to all of these products.

(4) Pro-Guard Double Duty joins two of these materials, polyester/cellulose and polypropylene, through the ultrasonically bonding of a sheet of one to a sheet of the other. This provides the traditional two sheets of wrap but allows the user to wrap the tray or pack with both sheets at the same time as in the Kimberly-Clark One Step product rather than sequentially. No additional materials are added as a bonding agent or for any other reason.

(5) Pro-Guard Double Duty, like the other wrap products available, is intended to wrap other medical devices for exposure to saturated steam or ethylene oxide sterilization processes and to maintain sterilization for a reasonable time under reasonable conditions.

(6a) Sheets of two different materials were used rather than two sheets of the same material in an effort to provide the best characteristics of each for the end user. The cellulose/polyester (Pro-Guard) is used as the outside sheet for its non-irritating handling properties and good biobarrier

characteristics and 100% polypropylene is used on the inside as a strengthening member with its resistance to tear. Both materials are non toxic when used as directed for the purpose intended. The resulting product is puncture resistant, offers the same biobarrier qualities as other premium wrap products while allowing the user to save time by wrapping an item intended for sterilization once rather than twice.

(6b) Below is a listing of the nonclinical testing performed for this submission and discussion of the results.

Primary Skin Irritation Testing

The scores for primary skin irritation in the rabbit testing were 0.00 which indicates that Double Duty Pro-Guard should not cause irritation to an operator.

Sterilant Penetration

All survival and all kill points for biological indicators contained in Double Duty Pro-Guard were lower or very close to those for other wraps existing on the market.

Six Month Biobarrier Shelf-life Testing

The only positives concerning Double Duty Pro-Guard were made with the double wrapped packs which were more difficult to test due to the extra layers. The positive test results were very probably caused by contamination.

Ethylene Oxide Residuals and Outgassing

The low level of residuals indicate that Double duty Pro-Guard allows free movement of EO.